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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,177	10/25/2001	Avi J. Ashkenazi	GNE.2630P1C90	4438

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EXAMINER

SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/016,177

Applicant(s)

ASHKENAZI ET AL.

Examiner

Christine J. Saoud

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-65, 68-70 and 74-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-65, 69, 70 and 74-77 is/are rejected.
- 7) ☒ Claim(s) 68 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 01/26/05.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: seq alignments

Art Unit: 1647

DETAILED ACTION

Claims 58-65, 68-69, and 74 have been amended and claims 1-62, 66-67 have been canceled in the paper filed 22 December 2004. Claims 58-65, 68-70 and 74-77 are pending in the instant application. It is noted that the status of claim 74 is indicated as "previously presented" which is incorrect. It is clearly "currently amended" (dependency has been changed). Applicant should make sure that the claim status is correctly reflected in the next response filed.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 22 December 2004 have been fully considered but are not persuasive. New grounds of rejection are also presented below. The delay in making the new grounds of rejection is regretted.

Information Disclosure Statement

Applicant's IDS filed 26 January 2005 has been received and considered.

Priority

As indicated in the previous Office action and reiterated by Applicant in the response of 22 December 2004, the instant application has been granted priority based on the fetal hemoglobin induction assay which was first disclosed in PCT/US00/04341,

Art Unit: 1647

which was filed February 18, 2000. All prior art rejections are based on this priority date.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 58-61, 74-77 are rejected under 35 U.S.C. 102(e) as being anticipated by Parham et al. (U.S. Pat. No. 6,586,228) for the reasons of record and for those reasons provided below.

Applicant argues at page 20 of the response that Parham et al. has only 66.2% sequence identity to the entire length of SEQ ID NO:351, that Parham et al. does not disclose 100% sequence identity to the full length coding region and Parham et al. does not disclose a polypeptide having 100% sequence identity to the polypeptide of SEQ ID NO:352. However, the rejection is only being made over claims which are directed to nucleic acid molecules that have 80-95% sequence identity to SEQ ID NO:351, wherein the encoded polypeptide has fetal hemoglobin inducing activity.

Note the specification sets for the following definition on page 123, lines 24-28:

"Percent (%) amino acid sequence identity" with respect to the PRO polypeptide sequences identified herein is defined as the percentage of amino acid residues in a

Art Unit: 1647

candidate sequence that are identical with the amino acid residues in the specific PRO polypeptide sequence, after aligning the sequences and introducing gaps, if necessary, to achieve the maximum percent sequence identity, and not considering any conservative substitutions as part of the sequence identify.

The nucleic acid molecule of Parham et al. has 98.1% identity with the sequence of SEQ ID NO:351, therefore, the structural limitations of the claims are met. Parham et al. is silent to the biological activity of inducing fetal hemoglobin for the encoded protein, however, based on the degree of identity of the nucleic acids and the encoded polypeptide, the biological activity of the encoded protein would be inherent, absent evidence to the contrary. Applicant should note that an argument to the contrary may serve as the basis of an enablement rejection of the claims.

Claims 58-65, 69-70, 74-77 are rejected under 35 U.S.C. 102(e) as being anticipated by Thompson et al. (U.S. Pat. No. 6,610,286).

Thompson et al. disclose a polypeptide which comprises the amino acid sequence of SEQ ID NO :14. The amino acid sequence of SEQ ID NO:14 of Thompson et al. is identical to that of the claimed polypeptide amino acid sequence of SEQ ID NO:352. Thompson et al. identifies SEQ ID NO :14 as amino acid sequence for the IL-20 receptor B subunit and indicates that SEQ ID NO:15 (N-terminally and C-terminally truncated form of SEQ ID NO:14) as the soluble form of the receptor (see column 5, lines 7-10). Based on this disclosure, the location of the signal peptide is deduced as positions 1-29 of SEQ ID NO:14, which corresponds to the indicated signal sequence (Figure 142 of the instant application). Thompson et al. disclose a nucleic acid

molecule (SEQ ID NO:13) that encodes the polypeptide. This nucleic acid is 99.4% identical to the nucleic acid molecule of SEQ ID NO:351 over nucleotides 234-1203.

The nucleic acid molecule of Thompson et al. has 99.4% identity with the sequence of SEQ ID NO:351, therefore, the structural limitations of the claims are met. Thompson et al. is silent to the biological activity of inducing fetal hemoglobin for the encoded protein, however, because the encoded polypeptide is identical in structure, the biological activity of the encoded protein would be inherent, absent evidence to the contrary. Applicant should note that an argument to the contrary may serve as the basis of an enablement rejection of the claims. Therefore, the instant invention is anticipated by Thompson et al., absent evidence to the contrary.

Claims 58-65, 69-70, 74-77 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al. (Pre-grant publication U.S. 2003/0175778, published Sept. 18, 2003 with priority to June 5, 1998. A copy of Figure 1A from the provisional application is provided to establish grant of priority).

Ni et al. disclose a polypeptide which comprises the amino acid sequence of SEQ ID NO:2. The amino acid sequence of SEQ ID NO:2 of Ni et al. is identical to that of the claimed polypeptide amino acid sequence of SEQ ID NO:352. Ni et al. identifies SEQ ID NO :2 as the amino acid sequence for interferon receptor HKAEF92 and indicates that the predicted leader sequence is amino acids 1-29 (see [0019]). Ni et al. teach a nucleic acid molecule which has 99.7% identity with the sequence of SEQ ID NO:351, therefore, the structural limitations of the claims are met. Since the amino acid

Art Unit: 1647

sequence of the encoded protein is identical to that of the instant specification, the functional limitations of the claims should also be met (inherent property of the protein having the amino acid sequence disclosed in the instant specification). Applicant should note that an argument to the contrary may serve as the basis of an enablement rejection of the claims. Ni et al. further disclose vectors and host cells as intended by the claims, therefore, the instant invention is anticipated by Ni et al., absent evidence to the contrary.

Claim Objections

Claim 68 is objected to for depending on a rejected claim. If claim 68 were written as an independent claim (i.e. an isolated nucleic acid comprising the nucleic acid sequence of SEQ ID NO:351), the claim would be allowable.

Conclusion

No claim is allowed.

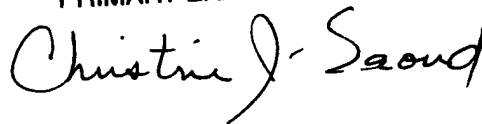
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1647

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINE J. SAOUD
PRIMARY EXAMINER

A handwritten signature in black ink that reads "Christine J. Saoud". The signature is written in a cursive style, with the first name "Christine" and last name "Saoud" clearly legible, and the middle initial "J." in between.